FDA



# Class 2 Device Recall mcompass 2channel Balloon Catheters



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## Class 2 Device Recall mcompass 2channel Balloon Catheters

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| **Date Initiated by Firm** | June 14, 2017 |
| **Create Date** | August 25, 2017 |
| **Recall Status[1]** | Open[3], Classified |
| **Recall Number** | Z-3072-2017 |
| **Recall Event ID** | 77706[23] |
| **510(K)Number** | K120088[24] K143031[25] |
| **Product Classification** | Catheter, rectal[26] - **Product Code** GBT[27] |
| **Product** | mcompass 2-channel Balloon Catheters<br><br>The mcompass Biofeedback Anorectal Manometry System is for use on patients requiring anorectal pressure studies. mcompass Anorectal Manometry System (RMD-001-001) which includes a FOB component connected to the balloon catheter to inflate and deflate and a medical grade tablet PC to run the software. The software is not included in the recall, only the balloon catheter component. |
| **Code Information** | Part # RMD-002-004, Lot No #'s 160627-10 and 160627-11. |
| **Recalling Firm/ Manufacturer** | Medspira, Llc<br>2718 Summer St NE<br>Minneapolis MN 55413-2820 |
| **For Additional Information Contact** | Paul Bradik<br>612-789-0013 |
| **Manufacturer Reason for Recall** | Potential failure in the balloon bond in the inner catheter stem, leading to the separation of the balloon from the inner stem, leaving it in the rectal cavity. |
| **FDA Determined Cause [2]** | Employee error |
| **Action** | The firm Medspira plans to contact all foreign and domestic consignees in regards to the recall. International consignees are to destroy recalled product by cutting the catheter shaft and balloon with scissors. It is also requested that their own customers be notified of the recall. Medspira plans to provide product replacement. Domestic customers are asked to return affected catheters to the recalling firm. Medspira indicates that they will cove shipping costs and replacements. All consignees are asked to complete and return the attached recall response form. For further questions please call, (612) 789-0013. |
| **Quantity in Commerce** | 355 catheters (255 US - 100 foreign. ) |
| **Distribution** | Worldwide Distribution - US Distribution to the states of :CA, FL, IA, ID, and TX., and to the countries of : Austria, Italy, Malaysia, Philippines, Sweden, and United Kingdom |
| **Total Product Life Cycle** | TPLC Device Report[28] |

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[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA